**MODIFICATION**

**REQUEST TO USE ANIMALS**

**INSTRUCTIONS**

**COMPLETION OF FORM**

For proposed changes (other than addition of personnel) to an approved “Request to Use Animals” (protocol) complete this “Modification – Request to Use Animals”. To add personnel to an approved protocol, complete and submit the “Addition of Personnel” form (file name: Add personnel).

Answer all questions that apply in a manner comprehensible to the layperson and define discipline specific terminology and abbreviations the first time they are used. Enter all responses in the answer boxes provided. For Yes/No questions and those that are not applicable (N/A), check the box or insert an “X” to the right of the appropriate response. Guidance in responding to the questions is provided by resting the cursor over the highlighted word in each section or by reviewing the “Comment” box in the margin of each page (Word version).

**SUBMISSION**

Submit the completed document electronically as an email attachment, along with other required forms (e.g., hazardous substances), to the Institutional Animal Care and Use Committee (IACUC) Coordinator at the institution to which the original protocol was submitted. Only word processed (minimum font size of 11 point) submissions will be accepted. Final approval cannot be granted until a signed *Investigator Signature* page is received.

**NOTICE TO NATIONAL INSTITUTES OF HEALTH GRANTEES**

According to the NIH Grants and Policy Statement, Part II, section 8.1.2.5, NIH grantees must obtain prior approval from the NIH awarding Institute or Center for animal use protocol modifications that result in a change in scope of a funded project. Potential indicators of a change in scope can be viewed at <http://grants.nih.gov/grants/policy/nihgps_2010/nihgps_ch8.htm>.

**GENERAL**

All changes must be approved by the IACUC before they are implemented. Some changes may be of sufficient magnitude as to require a new protocol. Contact the IACUC Coordinator at your institution for advice.

**MODIFICATION - REQUEST TO USE ANIMALS**

Protocol Number:

Protocol Title:

**1. ADDITIONAL ANIMALS** **N/A:**

*Indicate the number of additional animals that will be needed & provide a justification for the request. If no new animals are requested, then mark N/A and move to Section 2.*

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**2. PROCEDURAL ADDITIONS or MODIFICATIONS** **N/A:**

*Describe any proposed procedural changes or additions involving living animals & include a justification for the change. If none are proposed, then mark N/A and move to Section 3.*

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**2.A.** Describe the training/experience of each protocol participant as it relates to the new procedure(s) listed above.

**2. B. Postprocedural care and monitoring:**

*If the Modification Request includes any procedural additions or modifications, then complete the following.*

1) Describe the post-procedural care and monitoring for both surgical (after recovery from anesthesia) and nonsurgical procedures. Identify the parameters being monitored and the frequency and duration of monitoring for each study related procedure. Include how records of the care will be maintained and their location.

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2) Identify by title who will conduct the care and monitoring*.*

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3) List any analgesics or other medically related pharmaceutical agents that animals may receive. Include **a)** dose, **b)** route of administration **c)** frequency of administration, and **d)** duration of therapy.

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4) List the criteria that will be used to determine that relief from pain or distress is needed and how the adequacy of that relief will be assessed.

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5) List the humane endpoints that will be used to euthanize an animal or otherwise remove an animal from a study.

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**2.C.** *According to the NIH Grants and Policy Statement, Part II, section 8.1.2.5., NIH grantees must obtain prior approval from the NIH awarding Institute or Center for animal use protocol modifications that result in a change in scope of a funded project. Potential indicators of a change in scope can be viewed at:*

[*http://grants.nih.gov/grants/policy/nihgps\_2010/nihgps\_ch8.htm*](http://grants.nih.gov/grants/policy/nihgps_2010/nihgps_ch8.htm)

**Will the new procedure(s) described above change the scope of the funded**

**project? YES: NO:**

**If YES, please contact your Office of Research and Sponsored Programs.**

**2.D. Chemical/compound administration to live animals**

*If the Modification Request involves the administration of any chemicals to animals that were not described in the original protocol, then complete the following.*

Are all of the chemicals (e.g., test compounds, receptor agonists/antagonists, labeling compounds, anesthetics, analgesics, euthanasia agents, etc.) administered to live animals commercially available pharmaceutical preparations intended for animal or human use?

**Yes: No:**

**If not,** then complete the following for each product.

Identify the chemical/compound and describe how it is prepared and stored to assure appropriate purity, sterility and suitability for administration to animals. Indicate the shelf life of the prepared product.

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*Are all of the chemicals/compounds listed above pharmaceutical grade?***Yes: No:**

**If not,** then list them and provide a justification for not using a pharmaceutical grade preparation.

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**3. New or revised pain/distress classification**  **N/A:**

For any protocol modification that includes a new or revised pain/distress producing procedure, place an “X” in front of the appropriate category(ies) and identify the procedure(s). Otherwise mark N/A and move to Section 3.

**- Category C** - Procedures that involve no more than momentary or slight pain or distress.

List procedures:

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Number of animals in category C:

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**- Category D** - Procedures that may cause more than momentary or slight pain or distress for which appropriate analgesia, anesthesia or tranquilization is provided.

List procedures:

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Number of animals in category D:

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**- Category E** - Procedures that may cause pain or distress which are not relieved by analgesia, anesthesia, or tranquilization.

List procedures:

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Number of animals in category E:

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For Category E procedures: Provide a detailed scientific justification for withholding analgesia, anesthesia, and tranquilization.

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**4. ALTERNATIVES TO THE USE OF ANIMALS AND PAIN OR DISTRESS PRODUCING PROCEDURES**

*Provide a written narrative description of the methods and sources that were used to determine that suitable alternatives to the use of animals and to the pain or distress producing procedures described in the protocol are not available. Provide an explanation for alternatives that were identified but deemed unsuitable. Literature searches must include a) databases searched, b) the date of the search, c) the years covered by the search (minimum 10 years), and d) the search strategy including keywords used. At least two acceptable information sources must be used. The response must address the three R’s: Replacement models, Refinements in technique, and Reduction in animal numbers. Information sources that are commonly used include* [*http://www.pubmed.gov*](http://www.pubmed.gov)*,* [*http://agricola.nal.usda.gov*](http://agricola.nal.usda.gov)*,* [*http://www.nal.usda.gov/awic*](http://www.nal.usda.gov/awic)*, and specifically for teaching activities,* [*http://oslovet.veths.no*](http://oslovet.veths.no)*.*

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**5. OTHER CHANGES** **N/A:**

*Describe any other proposed changes to the protocol & include a justification for the change.*

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**4. MODIFICATION APPROVAL**

*Select the institution to which the Modification Request will be submitted from the drop down menu below.*

Approval of the protocol modification is indicated by the signatures of the institution-specific individuals identified below. The individuals signing confirm that they have reviewed the modification and find it to be in compliance with applicable animal care and use regulations and institutional policies.

**Approval Signatures:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Facility Director

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IACUC Member

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Attending Veterinarian

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IACUC Chairperson

**INVESTIGATOR SIGNATURE**

I request the above described modifications to my previously approved “Request to Use Animals”. I acknowledge that all assurances listed in the original “Request to Use Animals” remain in effect.

**Principal Investigator:**

Name:

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**OR**

**Co-Investigator:**

Name:

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_